



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCESOPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361**MEMORANDUM**

DATE: 08/15/02

SUBJECT: **PP# 8F5023. Residue Chemistry Review for Cyfluthrin - Proposal for Tolerances of Residues in/on Soybean and Field Corn.**

DP Barcode:	D250002	PRAT Case:	290427
Submission No.:	S549586	Caswell No.:	None
Chemical No.:	128831	Class:	Insecticide
Trade Name:	Baythroid 2	EPA Reg No.:	3125-351
40 CFR:	§180.436		

TO: G. LaRocca /PM Team 13
IRB/RD (7505C)FROM: Yan Donovan, Chemist
RAB2/HED (7509C)*Yan Donovan*THRU: Richard A. Loranger, Branch Senior Scientist
RAB2/HED (7509C)*R. Loranger*

EXECUTIVE SUMMARY OF DEFICIENCIES

- A revised Section B for the 2 lb/gal EC must be submitted correcting the typographical error under the soybean use directions (i.e. 0.44 lb ai/A should read 0.044 lb ai/A). A revised section B is needed to clarify the PHIs for corn to indicate a 0-day PHI for forage and a 21-day PHI for grain and fodder (stover).
- A revised Section F proposing tolerance for *Soybean, seed* instead of “Soybean, beans” at 0.03 ppm. Tolerances for “Corn, field, forage and “Corn, field, fodder” should be listed as *Corn, field and pop, forage* and *Corn, field and pop, stover*, respectively.

INTRODUCTION

Bayer Corporation has submitted a petition to establish permanent tolerances for residues of cyfluthrin in/on soybean and field corn commodities. Volumes of residue chemistry data were submitted with this petition (MRID 44629601 through 05) as well as an administrative volume (no MRID assigned). These data were originally reviewed by Dynamac Corporation under contract to HED. That document has been revised by HED to reflect Agency policies and been incorporated into this review.

cc: Y.W. Donovan, RAB2 reading file, PP# 8F05023.

Cyfluthrin

PC Code 128831

(DP Barcode D250002)

**Permanent Tolerance Petition (PP#8F5023)
For Use On Soybean and Field Corn**

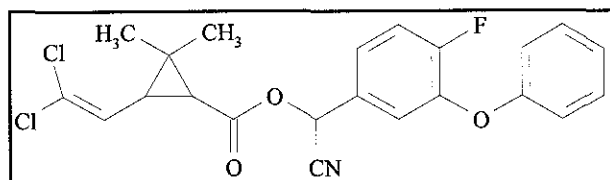
July 27, 2000

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
1910 Sedgwick Road
Building 100, Suite B
Durham, NC 27713

CYFLUTHRIN



PERMANENT TOLERANCE PETITION (PP#8F5023)
FOR USE ON SOYBEAN AND FIELD CORN

PC CODE 128831

(DP Barcode D250002)

INTRODUCTION

Bayer Corporation has submitted a petition to establish permanent tolerances for residues of cyfluthrin in/on soybean and field corn commodities. The petitioner has proposed the following tolerances for residues of cyfluthrin [cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] in or on:

Soybean, bean	0.03 ppm
Soybean, forage	8.0 ppm
Soybean, hay	4.0 ppm
Corn, field, forage	3.0 ppm
Corn, field, fodder	6.0 ppm

A petition requesting the use of cyfluthrin (2 lb/gal emulsifiable concentrate, EC) for the control of insect pests on soybeans was originally made by Mobay Corporation (a former subsidiary of Bayer), in conjunction with proposed uses on a variety of crops (PP#9F3731/9H5574). The Agency's review (CB Nos. 5039-5041, 5242, and 5243, H. Fonouni, 11/17/89) of this petition cited numerous deficiencies in the data supporting the uses on alfalfa, sweet corn, soybeans, and sunflowers and recommended against tolerances for these commodities. As a result, Mobay withdrew its request for use on these crops. Subsequently, Miles, Inc. (also a former subsidiary of Bayer) submitted a new pesticide tolerance petition (PP#3F4309/3H5686) to support the use of cyfluthrin (2 lb/gal EC) on alfalfa, sunflowers, sweet corn, and soybeans. The Agency's initial review (DP Barcodes D198387 and D198399, J. Garbus, 5/25/95) of the data supporting this petition also cited numerous deficiencies, including the need for a soybean processing study. The other deficiencies pertaining to the uses on alfalfa, sunflowers, and sweet corn were eventually resolved (DP Barcode D219550, J. Garbus, 10/10/95, and DP Barcode D221081, J. Garbus,

1/23/96), and tolerances were established for cyfluthrin residues in/on commodities from these crops. However, the petitioner chose to delete the requested use on soybeans.

In conjunction with the current petition, Bayer is requesting an amended registration of its 2 lb/gal EC formulation of cyfluthrin (Baythroid® 2 Emulsifiable Pyrethroid Insecticide; EPA Reg. No. 3125-351) to include uses on soybeans and field corn. This 2 lb/gal EC is currently registered for use as foliar applications on the following crops: alfalfa, carrots, citrus (AZ and CA only), cotton, peppers, potatoes, radishes, sorghum, sugarcane, sunflowers, sweet corn, and tomatoes.

Permanent tolerances have been established [40 CFR §180.436] for residues of cyfluthrin in/on a number of plant and animal commodities. Tolerances have been established on plant commodities ranging from 0.01 ppm for corn grain, peppers, and potatoes to 300 ppm for aspirated grain fractions. Tolerances have also been established on animal commodities ranging from 0.01 ppm for poultry commodities to 15 ppm for milk fat. A tolerance of 0.05 ppm has been established in food or feed commodities exposed to the insecticide during treatment of food-handling or feed-handling establishments where food and food products, or feed and feed products, are held, processed, prepared, or served.

There are Codex Maximum Residue Limits (MRLs) established for residues of cyfluthrin in/on apples, milk, cotton seed, maize, peppers, rape seed, tomatoes, and sweet corn ranging from 0.01-0.5 ppm.

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. The Agency has previously concluded that adequate data are available to fulfill product chemistry data requirements for cyfluthrin.

OPPTS GLN 860.1200: Proposed Uses

2. The proposed use directions for field corn and soybeans are adequate. **However, a revised product label for the 2 lb/gal EC must be submitted correcting the typographical error under the soybean use directions (i.e. 0.44 lb ai/A should read 0.044 lb ai/A). A revised section B is needed to clarify the PHIs for corn to indicate a 0-day PHI for forage and a 21-day PHI for grain and fodder (stover).**

OPPTS GLN 860.1300: Nature of the Residue

3. The Agency has previously concluded that the nature of the residues of cyfluthrin in plants and animals is adequately understood based on plant metabolism studies with cotton,

soybeans, potatoes, apples, wheat, and tomatoes and livestock metabolism studies on poultry and cows. The residue of concern in plants and animals is cyfluthrin *per se*.

OPPTS GLN 860.1340: Analytical Methods

- 4a. **Plants.** Adequate GC/ECD or GC/MS-SIM methods, which are modification of the GC/ECD Method 85823, were used for collecting data on cyfluthrin residues in soybeans processed fractions and field corn commodities. The validated LOQ is 0.01 ppm for soybeans and corn grain, 0.05 ppm for corn forage, and 0.5 ppm for corn fodder. An enforcement method is available (GC/ECD Method 85823) for regulating tolerances of cyfluthrin in/on plant commodities; this method has a validated LOQ of 0.01 ppm.
- 4b. **Animals.** An adequate GC/ECD method is available for enforcing tolerances for cyfluthrin residues in animal commodities and is published in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

5. The petitioner has previously submitted data describing the testing of cyfluthrin through FDA Multiresidue Methods. These data indicate that adequate recoveries of cyfluthrin have been obtained under FDA's multiresidue protocols.

OPPTS GLN 860.1380: Storage Stability Data

6. Adequate storage stability data are available to support the field trials and processing studies on corn and soybeans.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

7. This matter is being addressed in HED memo of 08/15/02, Y. Donovan, D262353.

OPPTS GLN 860.1500: Crop Field Trials

8. **Soybeans.** The available soybean field trial data are adequate and support the proposed use of the 2 lb/gal EC formulation on soybeans. Residues of cyfluthrin were 0.1-7.25 ppm in/on forage, 0.46-3.2 ppm in/on hay, <0.01-0.02 ppm in/on beans, and 0.49- 2.66 ppm in/on straw. The data indicate that the proposed tolerances for residues in/on soybean seed (0.03 ppm), soybean forage (8.0 ppm) and hay (4.0 ppm) are adequate.
- 9a. **Field Corn.** The submitted field corn residue data are adequate and support the proposed use of cyfluthrin (2 lb/gal EC; Baythroid® 2E) on field and pop corn. Residues of cyfluthrin were 0.66-2.24 ppm in/on 44 samples of forage harvested immediately (0-day) following the last of three foliar applications totaling 0.15 lb ai/A, and residues of cyfluthrin were <0.50-3.47 ppm in/on 44 samples of fodder harvested ~21 days following the last of four foliar

applications totaling 0.2 lb ai/A. When adjusted to a standard 83% dry weight, the highest average field trial (HAFT) residues in/on fodder were 4.94 ppm. Residues of cyfluthrin were <0.01 ppm all samples of grain (n=68) harvested at maturity, 14-35 days following the last of four foliar applications totaling 0.2 lb ai/A.

- 9b. Tolerances of 0.01 ppm have been established for residues of cyfluthrin in/on fodder, forage, and grain of field and pop corn [40 CFR §180.436] resulting from the at planting use of a 2.1% granular MAI (multiple active ingredient) formulation, containing cyfluthrin at 0.1%. These residue levels are negligible compared to the residues from foliar use. The proposed tolerances for cyfluthrin residues in/on corn fodder (6.0 ppm) and corn forage (3.0 ppm) are adequate. The existing 0.01 ppm tolerance on corn grain is adequate to cover the proposed use plus the at planting use.
- 9c. In addition to the at planting use on corn, corn grain has also a proposed post-harvest use (PP#5F4475, D262353), with residue level of 2.0 ppm. Compared to the post-harvest use, residues on corn grain from at planting use and the subject foliar uses are negligible. Therefore, the corn grain tolerance will be determined by the residues from the post-harvest use in PP# 5F4475.

OPPTS GLN 860:1520: Processed Food/Feed

10. The submitted soybean processing study is adequate and indicates that residues of cyfluthrin do not concentrate in soybean processed commodities. Following four foliar applications of cyfluthrin (2 lb/gal EC) at 0.22 lb ai/A/application (5x the maximum proposed rate), residues of cyfluthrin were 0.09 ppm in/on soybean seeds (RAC) harvested 45 days after the last treatment. Following processing of the above seeds, residues of cyfluthrin were <0.01-0.02 ppm in/on samples of hulls, meal, soapstock and crude and refined oil.
11. The submitted corn grain processing study is adequate and indicates that tolerances on corn grain processed commodities and aspirated grain fractions (AGF) are not necessary to support the proposed use of cyfluthrin (2 lb/gal EC) as a foliar application to field corn. Residues of cyfluthrin were <0.01 ppm in/on all 6 subsamples of corn grain harvested 21 days following the last of four foliar applications of cyfluthrin (2 lb/gal EC) totaling 1.0 lb ai/A (5.7x the proposed rate). Residues in corn aspirated grain fractions and processed commodities resulting from the proposed use are unlikely to exceed the current 0.01 ppm tolerance for cyfluthrin residues in/on corn grain.

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

12. The proposed label permitting the planting of rotational crops as soon as practical after the last application is acceptable based on reviews conducted by the Environmental Fate and Effects Division in 1989/1990.

Other Considerations:

With the exception of maize (MRL of 0.05 mg/kg), there are no established Codex MRLs for residues of cyfluthrin in/on the commodities discussed in the subject petition. Codex MRLs are currently expressed in terms of cyfluthrin *per se*. Although HED could consider harmonizing the existing field corn grain tolerance (0.01 ppm) with the Codex maize MRL, the co-pending stored grain use will require a much higher tolerance for corn grain.

RECOMMENDATIONS

Pending the results of the forthcoming human health risk assessment, HED does not object to the establishment of cyfluthrin tolerances in/on soybean and corn commodities. However, the petitioner should submit revised use directions (see Conclusion 2). The proposed tolerance for "Soybean, beans" (0.03 ppm) should be listed as *Soybean, seed*. Tolerances for "Corn, field, forage and "Corn, field, fodder" should be listed as *Corn, field and pop, forage* and *Corn, field and pop, stover*, respectively.

DETAILED CONSIDERATIONSOPPTS 830 Series GLNs: Product Properties

Adequate product chemistry data for the cyfluthrin TGAI are available.

OPPTS GLN 860.1200: Directions for Use

Bayer proposes amending the label for a currently registered 2 lb/gal EC formulation of cyfluthrin (Baythroid® 2, EPA Reg. No. 3125-351) to include uses on soybeans and corn (field, pop, and seed). The petitioner has submitted a draft revision of the Baythroid® 2 label including use directions for soybeans and field corn. The 2 lb/gal EC is proposed for multiple applications to field, pop or seed corn at 0.0125-0.044 lb ai/A/application beginning as a pre-plant application to the soil, with a minimum retreatment interval (RTI) of 7 days. Cyfluthrin may be applied as broadcast or directed applications using ground or aerial equipment. A minimum volume of 2 gal/A is specified for applications in water, and a minimum of 1 qt/A is specified for applications in sprayable vegetable oil. A maximum of four application would be allowed per season, with a total of three application up to the early dent stage and one application after the early dent stage. The label specifies a 21-day PHI and a seasonal maximum application rate of 0.175 lb ai/A. **However, field trials were conducted at 0-day PHI for corn forage, and 21-day PHI for fodder and grain. A revised section B is needed to clarify the PHIs for corn to indicate a 0-day PHI for forage and a 21-day PHI for grain and fodder (stover).**

RAB2 notes that concurrently there is a petition for post harvest use on field corn also (see petition for stored grain, PP#5F4475, D262353). However, there is no label restriction on pre-harvest treated corn grain being treated post harvest. Such a restriction would not be practical and is also not necessary in the case since pre-harvest residues are negligible compared to those from post-harvest use.

For soybeans, the 2 lb/gal EC is proposed for broadcast foliar applications at 0.0125-0.044 lb ai/A/application using ground or aerial equipment, with a minimum RTI of 7 days. The label specifies a minimum application volume of 2 gal of water/A and PHIs of 15 days for forage and 45 days for beans or dry vines. The maximum proposed seasonal application rate is 0.175 lb ai/A. The use directions for soybeans contain a typographical error under the allowed application dosage. A maximum single dose rate of 0.44 lb ai/A is listed; however, this value should read 0.044 lb ai/A. A revised product label for the 2 lb/gal EC must be submitted correcting the typographical error under the soybean use directions.

Conclusions: The proposed use directions for field corn and soybeans are adequate. However, a revised product label for the 2 lb/gal EC must be submitted correcting the typographical error under the soybean use directions (i.e. 0.44 lb ai/A should read 0.044 lb ai/A). A revised section B is needed to clarify the PHIs for corn to indicate a 0-day PHI for forage and a 21-day PHI for grain and fodder (stover).

OPPTS GLN 860.1300: Nature of the Residue - Plants

The nature of the residue in plants is understood based upon adequate studies conducted with [¹⁴C]cyfluthrin on cotton and soybeans (PP#3G2976), potatoes (PP# 4F3046), apples (PP#4F3046), wheat and tomatoes (PP#9F3731). The residue of concern in plants is cyfluthrin *per se*.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

The nature of the residue in animals is understood based upon acceptable ruminant and poultry metabolism studies (PP#4F3046, K. Arne, 5/18/84; and PP#4G2976, R. Loranger, 2/23/84). The residue of concern in animals is cyfluthrin *per se*.

OPPTS GLN 860.1340: Residue Analytical Methods - Plants

A GC/ECD method is available for enforcing tolerances for cyfluthrin residues in/on plant commodities. This method was previously described in Mobay Report 85823 ("A Gas Chromatographic Method for Baythroid® 2 Residues in Crops", MRID 40301501) and has undergone successful petition method validation (PP#4F3046). This method was forwarded (3/88) to FDA for inclusion in PAM II (DP Barcodes D190671, D190675, and D190677, J. Morales, 5/5/94).

A modified version of Method 85823 was used to analyze soybean seeds and processed fractions reviewed in this petition. The analyses were conducted at Ricerca, Inc., Department of Environmental Sciences, Painesville, OH. Briefly, residues were extracted twice with methanol:water (4:1, v/v), filtered, partitioned into acetone:chloroform (1:2, v/v), and filtered through sodium sulfate. The residues were then concentrated to dryness, redissolved in hexane and partitioned into acetonitrile (ACN). Residues were cleaned-up by using an alumina column eluted with hexane:ethyl acetate (9:1, v/v). Residues in hull samples were also further purified using a C₁₈ cartridge eluted sequentially with ACN:water at 1:1 and 9:1 (v/v). The purified residues were evaporated to dryness, redissolved in hexane, and analyzed using GC/ECD. The method LOQ and LOD is 0.05 and 0.01 ppm respectively.

Recoveries of cyfluthrin were 70-107% from soybean seed and processed commodities fortified with cyfluthrin at 0.01-0.20 ppm (Table 1). Apparent residues of cyfluthrin were <0.01 in/on all control samples. Adequate representative sample calculations and chromatograms were submitted.

Table 1. Recoveries of cyfluthrin from fortified crop control samples analyzed using a GC/ECD method (Method 85823).

Crop/ MRID	Matrix	Fortification Level (ppm)	# of samples	% Recovery of cyfluthrin	Ave.± SD
Soybean 44629601	Seed	0.01-0.10	5	70-98	86.6±11.5
	Hulls	0.05, 0.20	2	81, 90	NA
	Meal	0.05, 0.20	2	92, 107	NA
	Crude Oil	0.05, 0.20	2	82, 75	NA
	Refined Oil	0.05, 0.20	2	78, 74	NA
	Soapstock	0.05, 0.20	2	94, 78	NA

In the corn field trials and processing study, cyfluthrin residues in/on corn grain, forage, and fodder were determined using a modified version of Method 85823, in which mass spectrometry in the select ion mode (MS-SIM) was used for detection of cyfluthrin instead of ECD. The analyses were conducted by the Residue Analysis Laboratory at the Bayer Research Park (BRP) in Stilwell, KS.

Briefly, residues were extracted twice with methanol:water (4:1, v/v), filtered, and concentrated. Water and sodium chloride were added and the acidity was adjusted to pH 1. Residues were partitioned into hexane, filtered through sodium sulfate, concentrated to near dryness, and re-dissolved in hexane. Residues were then cleaned-up by florisil and silica gel chromatography. The column eluants were evaporated to dryness, redissolved in cyclohexane, and analyzed by GC/MS-SIM using the 226 m/z ion for quantitation. The validated LOQ is 0.01 ppm for grain, 0.05 ppm for forage, and 0.5 ppm for fodder.

To validate the above GC/MS-SIM method, the registrant fortified control samples with cyfluthrin at 0.05 and 4.0 ppm for forage, 0.01-0.05 ppm for grain, and 0.5-4.0 ppm for fodder. Recoveries of cyfluthrin were 75-120% from forage, 90-125% from grain, and 70-119% from fodder (Table 2). Apparent residues of cyfluthrin were <LOQ in/on all control samples. Adequate representative sample calculations and chromatograms were submitted.

Table 2. Recoveries of cyfluthrin from fortified crop control samples analyzed using a GCMS-SIM method.

Crop/ MRID	Matrix	Fortification Level (ppm)	# of samples	% Recovery of cyfluthrin	
				Range ^a	Ave. \pm SD
Field Corn 44629605	Forage	0.05, 4.0	17	75-120	95 \pm 13
	Grain	0.01, 0.02, 0.05	19	90-125 (1)	105 \pm 11
	Fodder	0.5, 2.0, 3.0, 4.0	22	70-119	93 \pm 14
Field Corn 44665701	Grain	0.01, 0.02	7	95-110	103 \pm 5.7

^a Values in parentheses indicate the number of samples with a recovery outside the acceptable 70-120% range.

Conclusions:

The GC/ECD and GC/MS-SIM methods used for collecting data on cyfluthrin residues in soybeans and their processed fractions and field corn commodities are adequate. The validated LOQ is 0.01 ppm for soybeans and corn grain, 0.05 ppm for corn forage, and 0.5 ppm for corn fodder.

An enforcement method (GC/ECD Method 85823) is available for regulating tolerances of cyfluthrin in/on plant commodities; this method has a validated LOQ of 0.01 ppm.

OPPTS GLN 860.1340: Residue Analytical Methods - Animals

A GC/ECD method is available for enforcing tolerances for cyfluthrin residues in animal commodities and is published in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

The petitioner has previously submitted data (MRID 41355901) describing the testing of cyfluthrin through FDA Multiresidue Methods. These data, which have been forwarded to FDA for review, indicate that adequate recoveries of cyfluthrin have been obtained under FDA's multiresidue protocols (PP#4F3046, M. Bradley, 12/4/87).

OPPTS GLN 860.1380: Storage Stability Data

No new storage stability data were submitted with the current petition. However, storage stability data are available from numerous crops, including corn and soybean commodities, indicating that cyfluthrin is stable in frozen storage for the intervals used in soybean and field corn residue trials and processing studies (DP Barcodes D198397 and D198399, J. Garbus, 5/25/95).

OPPTS GLN 860.1500: Crop Field Trials

Soybean. No new soybean field trial data were submitted with the current petition. The petitioner cited data from seventeen soybean field trials (MRIDs 41001610 and 42864603) that were previously submitted in conjunction with the earlier petitions for use of cyfluthrin on soybeans (PP#9F3731/9H5574, H. Fonouni, 11/17/89; and PP#3F4309/#H5686, DP Barcodes D198397 and D198399, J. Garbus, 5/25/95). In one study (MRID 41001610), a total of 12 field trials were conducted in AR, GA, IL, IN, KS, MS, NE, and TN. Cyfluthrin (2 lb/gal EC) was applied to soybeans as four foliar applications at 8-21 day intervals at 0.044 lbs. ai/A/application for a total of 0.176 lb ai/A (1x). Samples of forage and hay were collected from 14-30 days post-treatment and samples of beans and straw were collected from 31-76 days post-treatment. Samples were stored frozen for up to 299 days prior to analyses. Residues of cyfluthrin were 0.1-7.25 ppm in/on forage (n=12), 0.46-1.05 ppm in/on hay (n=5), <0.01-0.02 ppm in/on beans, and 0.49 ppm in/on straw.

In another study (MRID 42864603), a total of 5 field trials were conducted in GA, IA (2), KS, and MS. Cyfluthrin (2 lb/gal EC) was applied to soybeans as four foliar applications at 6-8 day intervals at 0.044 lbs ai/A/application for a total of 0.176 lb ai/A (1x). Samples of forage and hay were collected from 8-15 days post-treatment and samples of beans and straw were collected from 45-54 days post-treatment. Samples were stored frozen for up to 440 days prior to analyses. The maximum residues of cyfluthrin found in these trials were 1.3 ppm in/on forage, 3.2 ppm in/on hay, <0.01 ppm in/on beans, and 2.66 ppm in/on straw.

It was concluded that geographic representation and number of tests conducted on soybeans are sufficient for the purposes of this petition. Only 17 field trials were conducted and current Agency Guidance (OPPTS GLN 860.1500) requires a total of 20 field tests for soybeans; however, the studies were initiated prior to the issuance of the guidance (8/96) and the data are considered representative of the major U.S. soybean growing regions.

Conclusions.

The available soybean field trial data are adequate and support the proposed use of the 2 lb/gal EC formulation on soybeans. The data indicate that the proposed tolerances for residues in/on soybean seeds (0.03 ppm), soybean forage (8.0 ppm) and hay (4.0 ppm) are adequate.

Field Corn. Tolerances of 0.01 ppm have been established for residues of cyfluthrin in/on fodder, forage, and grain of field and pop corn [40 CFR §180.436] resulting from the at planting use of a 2.1% granular MAI formulation, containing cyfluthrin at 0.1%. Tolerances have also been established for residues of cyfluthrin in/on sweet corn forage, fodder, and K+CWHR at 30.0, 15.0, and 0.05 ppm, respectively.

To support the use of a 2 lb/gal EC formulation (Baythroid 2, EPA Reg. No. 3125-351) on field corn, the Bayer has submitted data (cited below) depicting cyfluthrin residues in/on field corn forage, fodder and grain from plants treated with four foliar applications of cyfluthrin (2 lb/gal EC) at 0.05 lb ai/A/application (~1x the proposed maximum rate).

44629605 Harbin, A.M. (1998) Baythroid 2 - Magnitude of the Residues in Field Corn, Lab Project No.: BD19CO05/108115. Unpublished study prepared by Bayer Corporation.
{OPPTS 860.1500}

A total of 22 tests were conducted on field corn during 1997 in NY, GA, IN (2), KS, NE, MN (2), WI, IL(4), MI, OH (2), IA (5), and TX. At each test site, cyfluthrin (2 lb/gal EC) was applied four times as a foliar spray application at 0.048-0.054 lb/A (~1x the maximum rate), for a total of 0.20 lb ai/A/season (about 1.15X maximum requested seasonal rate). The first application was made when corn plants were 6-10 inches in height. The second application was made 7 days prior to the late dough/early dent stage. The third application was made at late dough/early dent, and the fourth application was made at late dent to maturity, approximately 21 days prior to harvest. The minimum retreatment interval was ~7 days and all applications were made with ground equipment using spray volumes of 8-20 gallons of water/A. The proposed PHI is 21 days (presumably for forage, grain and fodder/stover).

For forage, a single control and duplicate treated samples were harvested from each test immediately following the third application (0-day PHI) at the late dough/early dent stage. In four of the tests (IN, KS, IL, and IA), forage was also sampled at approximately -3, 3, and 7 days relative to the third application to examine residue decline. At harvest, forage samples were 24-45% dry weight (D.W.). For grain and fodder, a single control and duplicate treated samples of each commodity were harvested from each test at normal crop maturity, approximately 21 days after the last application (DAT). In four tests (IN, KS, IL, and IA), grain and fodder were also sampled at approximately 14, 28, and 35 DAT to examine residue decline. The % D.W. for fodder samples was 28-79% at harvest, compared to the 83% D.W. specified for corn fodder in Agency guidance (OPPTS 860.1000).

All samples were frozen within 4 hours of collection and were shipped frozen to the analytical laboratory at Bayer Research Park (BRP), where they were stored at ≤-15 C until extraction for analysis. The maximum frozen storage interval was 191 days for forage, 173 days for fodder, and 201 days for grain. Data are available (DP Barcodes D198397 and D198399, J. Garbus, 5/25/95) indicating that cyfluthrin is stable in corn commodities stored frozen for the intervals reflected in this study.

Residues of cyfluthrin were determined by the GC/MS-SIM method described above. Recoveries of cyfluthrin from fortified control samples were 75-120% for forage, 90-125% for grain, and 70-119% for fodder. Apparent residues were <LOQ in/on all untreated field corn samples. Adequate representative sample calculations and chromatograms were submitted.

Residues of cyfluthrin were 0.66-2.24 ppm in/on 44 samples of forage harvested immediately (0-day) following the last of three foliar applications totaling 0.15 lb ai/A (Table 3). For fodder, residues of cyfluthrin were <0.50-3.47 ppm in/on 44 samples of fodder harvested ~21 days following the last of four foliar applications totaling 0.2 lb ai/A. The HAFT residues were 2.14 ppm for fodder from the test in Oxford, IN. However, when residue values are adjusted to a standard 83% D.W., the HAFT for fodder was 4.94 ppm from the test in Theilman, MN. Residues of cyfluthrin were <0.01 ppm all samples of grain (n=68) harvested at maturity, 14-35 days following the last of four foliar applications totaling 0.2 lb ai/A.

Residue decline data from both forage and fodder also indicated that cyfluthrin residues generally decreased at longer post-treatment intervals.

Geographic representation and the number of field corn trials conducted are adequate. The petitioner provided residue data on field corn from a total of 19 tests in Region 5 and one test each in Regions 1, 2, and 6.

Table 3. Residues of cyfluthrin in/on field corn forage and fodder harvested following 3 (forage) or 4 (fodder) applications of cyfluthrin (2 lb/gal EC) at 0.05 lb ai/A/application (0.2 lb ai/A/season; 1x).

Location	EPA Region	Application Data				% Dry matter	Cyfluthrin Residues ^b (ppm)
		Single Rate (lb ai/A)	# appl	Total Rate (lb ai/A)	PHI ^a (days)		
Forage							
North Rose, NY	1	0.049-0.052	3	0.15	0	30	2.24, 1.85
Hawkinsville, GA	2	0.048-0.05	3	0.15	0	34	0.95, 1.20
Howe, IN	5	0.05	3	0.15	-3	30	0.58 [0.61], 0.61
					0	31	1.81, 1.80
					2	32	1.74, 0.96
					7	34	1.12, 1.36
Stilwell, KS	5	0.05	3	0.15	-3	29	0.29, 0.32
					0	31	0.66, 0.75,
					3	31	0.56, 0.71,
					6	34	0.34, 0.45
Springfield, NE	5	0.05	3	0.15	0	28	0.96, 1.26
Campbell, MN	5	0.050-0.051	3	0.15	0	32	0.93, 1.17
Theilman, MN	5	0.050-0.051	3	0.15	0	24	1.63, 1.03
Arkansaw, WI	5	0.049-0.050	3	0.15	0	30	1.17, 1.14
Carlyle, IL	5	0.05	3	0.15	-3	25	0.53, 0.58
					0	27	1.04, 1.11
					2	27	0.86, 0.91 [1.00]
					7	26	0.76, 0.72
Greenville, IL	5	0.05	3	0.15	0	24	1.47, 1.65
Fillmore, IL	5	0.05	3	0.15	0	25	1.06, 0.87
Wyoming, IL	5	0.050-0.051	3	0.15	0	26	0.87, 0.67
Oxford, IN	5	0.05	3	0.15	0	27	1.08, 1.52
Conklin, MI	5	0.05	3	0.15	0	32	0.90, 1.60
New Holland, OH	5	0.049-0.054	3	0.15	0	25	1.05, 1.05
Greenfield, OH	5	0.049-0.051	3	0.15	0	31	1.05, 1.08
Bagley, IA	5	0.050-0.051	3	0.15	-5	33	0.79, 0.59
					0	34	1.24, 1.33
					3	37	1.65, 1.18
					8	45	0.77, 1.49 [0.77, 1.54]
Redfield, IA	5	0.049-0.051	3	0.15	0	38	1.47, 1.43
Berkley, IA	5	0.050-0.051	3	0.15	0	36	1.20, 1.25
Cooper, IA	5	0.050-0.051	3	0.15	0	37	1.44, 1.02

Table 2. *Continued.*

Location	EPA Region	Application Data				% Dry matter	Cyfluthrin Residues ^b (ppm)
		Single Rate (lb ai/A)	# appl	Total Rate (lb ai/A)	PHI ^a (days)		
Orient, IA	5	0.050-0.051	3	0.15	0	36	0.73, 0.92
Uvalde, TX	6	0.048-0.05	3	0.15	0	31	0.85, 1.92

Table 2. *Continued.*

Location	EPA Region	Application Data				% Dry matter	Cyfluthrin Residues ^b (ppm)
		Single Rate (lb ai/A)	# appl	Total Rate (lb ai/A)	PHI ^a (days)		
Fodder							
North Rose, NY	1	0.05	4	0.20	21	28	1.31, 1.74
Hawkinsville, GA	2	0.05	4	0.20	21	54	1.78, 1.79
Howe, IN	5	0.05	4	0.20	14	38	2.61, 2.66
					21	38	1.71, 1.94
					28	41	2.14, 2.35
					35	55	2.70, 1.58
Stilwell, KS	5	0.05	4	0.20	14	41	1.13, 1.02
					21	40	1.73, 0.65 [0.89, 0.62]
					28	42	0.77, 0.98
					34	44	0.52, 0.77
Springfield, NE	5	0.05	4	0.20	20	44	0.56, 0.85
Campbell, MN	5	0.05	4	0.20	21	55	0.55, 0.53
Theilman, MN	5	0.05	4	0.20	19	26	1.58, 1.52
Arkansaw, WI	5	0.05	4	0.20	20	37	2.24, 1.80
Carlyle, IL	5	0.05	4	0.20	14	65	1.47, 1.60
					20	64	1.27, 1.32
					28	78	1.04, 0.98
					35	79	0.67, 0.89
Greenville, IL	5	0.05	4	0.20	21	45	0.71, <0.5
Fillmore, IL	5	0.05	4	0.20	20	46	1.05, 1.13
Wyoming, IL	5	0.05	4	0.20	21	35	0.58, 0.85
Oxford, IN	5	0.05	4	0.20	19	42	1.36, 3.47 [0.91, 2.83]
Conklin, MI	5	0.05	4	0.20	21	30	1.19, 1.36
New Holland, OH	5	0.05	4	0.20	20	31	0.81, 0.63
Greenfield, OH	5	0.05	4	0.20	20	68	1.48, 1.49
Bagley, IA	5	0.05	4	0.20	14	37	1.31, 1.06
					21	42	1.42, 1.00
					28	43	1.23, 1.14
					35	61	1.54, 1.36
Redfield, IA	5	0.05	4	0.20	21	47	1.10, 1.06
Berkley, IA	5	0.05	4	0.20	23	63	0.88, 0.78
Cooper, IA	5	0.05	4	0.20	21	53	1.51, 1.46
Orient, IA	5	0.05	4	0.20	19	38	0.98, 1.18
Uvalde, TX	6	0.05	4	0.20	21	48	0.96, 1.97 [0.83, 2.38]

- ^a PHI = pre-harvest interval in days; the PHI is given relative to the 3rd application for forage and relative to the 4th application for fodder.
- ^b Bracketed values are from duplicate analyses of a one or two samples

Conclusions:

The submitted residue data on field corn are adequate and support the proposed use of the 2 lb/gal EC formulation on field corn. The data indicate that the proposed tolerances for cyfluthrin residues in/on corn fodder (6.0 ppm) and corn forage (3.0 ppm) are adequate. The use directions should be revised to specify a 0-day PHI for forage to match the conditions in the field trials. The existing corn grain tolerance of 0.01 ppm is adequate to cover the existing at planting use plus the proposed foliar uses.

OPPTS GLN 860.1520: Processed Food/Feed

Soybean. The petitioner submitted a soybean processing study (cited below) using seed from soybeans treated with cyfluthrin (2 lb/gal EC) at 5x the maximum proposed rate.

44629601 Burger, R. N. and Lenz, C. A. (1992) Cyfluthrin (2EC) - Magnitude of the Residue on Soybean Commodities, Lab Project No.: BD19SY01b/103825. Unpublished study prepared by Miles, Inc {OPPTS 860.1520}

In a single field trial in KS during the 1990 growing season, cyfluthrin (2 lb/gal EC) was applied four times to soybeans foliarly at 0.22 lb ai/A/application (5x the maximum proposed rate) at 7-day intervals, for a total of 0.88 lb ai/A. All applications were made with ground-based equipment at 19.2 gallons per acre.

Single bulk control and treated samples of mature soybean seed were harvested 45 days after the last application and placed in storage at <-15 C within 30 minutes of collection. Within 2 months, samples were shipped frozen to the Food Protein R&D Center, College Station, TX and processed into hulls, meal, crude and refined oil, and soapstock using simulated commercial procedures. Processing was completed within 143 days of harvest. Frozen seed (RAC) and processed commodities were shipped frozen to Miles, Inc (former subsidiary of Bayer) and later shipped frozen to Ricerca, Inc., Painesville, OH for analysis. The maximum frozen storage interval was 316 days for processed commodities and 459 days for seeds.

No new storage stability data were submitted with the current study. However, storage stability data are available for numerous commodities (DP Barcodes D198397 and D198399, J. Garbus, 5/25/95), including soybean seeds, indicating that cyfluthrin is stable in frozen storage for the intervals used in the above processing study.

Residues of cyfluthrin were determined by the GC/ECD method (Method 85823) described above. Recoveries of cyfluthrin were 70-95% from soybean seed fortified with cyfluthrin at 0.01-0.05 ppm and were 74-107% from processed commodities fortified at 0.05 and 2.0 ppm.

Apparent residues were <LOQ in/on all untreated soybean samples. Adequate representative sample calculations and chromatograms were submitted.

Following four foliar spray applications of cyfluthrin (2 lb/gal EC) at 0.22 lb ai/A/application (5x maximum proposed rate), residues of cyfluthrin were 0.09 ppm in/on soybean RAC from this one test harvested 45 days after the last treatment (Table 4). Residues in processed fractions were reduced by <0.1-0.2x.

Table 4. Residues of cyfluthrin in soybean commodities processed from seed harvested 45 days following the last of four applications of cyfluthrin (2 lb/gal EC) at 0.22 lb ai/A/application (5x proposed rate).

Crop/ MRID	Matrix	Application Data			Cyfluthrin Residues (ppm)	Concentration/ Reduction Factor
		Rate (lb ai/A)	# of applications	PHIS (days)		
Soybean/ 44629601	Seed (RAC)	0.22	4	45	0.09	NA
	Hulls				0.02	0.22
	Meal				<0.01 ^b	<0.11
	Crude Oil				0.01	0.11
	Refined Oil				0.02	0.22
	Soapstock				<0.01	<0.11

^a PHI refers to pre-harvest interval

^b LOD = 0.01 ppm

Conclusions:

The submitted soybean processing study is adequate and indicates that residues of cyfluthrin do not concentrate in/on soybean processed commodities. No tolerances are required for soybean processed commodities.

Corn. A tolerance of 300 ppm has been established for residues of cyfluthrin in/on aspirated grain fractions (AGF) [40 CFR §180.436]. No tolerances have been established on processed corn grain commodities.

Bayer has submitted a processing study (cited below) depicting the potential for concentration of cyfluthrin residues in corn grain processed commodities and AGF resulting from the proposed foliar use of the 2 lb/gal EC formulation on field corn.

44665701 Harbin, A.M. (1998) Baythroid 2 - Magnitude of the Residue in Aspirated Grain Fractions and Corn Processed Commodities, Lab Project No.: BD19CO06/108314
Unpublished study prepared by Bayer Corporation. {OPPTS 860.1520}

In a single field trial conducted in IN during 1997, cyfluthrin (2 lb/gal EC) was applied to field corn four times as a foliar application at 0.25 lb/A/application (5.7x the maximum rate), for a total of 1.0 lb ai/A. Applications were made when plants were 6 inches in height and at the dough stage, early dent stage, and dent stage. All applications were made with ground-based equipment using spray volumes of 9-16 gallons per acre.

A single 600 lb sample of mature corn grain was mechanically harvested 21 days post-treatment from both the control and treated plots. Samples were frozen within 3 hours of collection and shipped the same day to BRP, where samples were stored at ≤ -15 C. The control and treated samples were subsampled for analysis of grain at BRP, and the remaining samples were shipped frozen to the Food Protein Research and Development Center (FPRDC), Texas A&M University, where samples were stored at -15 C. Samples of AGF were generated prior to processing. Control and treated samples of grain were then processed using simulated commercial procedures into meal, flour, grits, starch, and dry-milled and wet-milled oil. After processing, RAC and processed samples were frozen and shipped back to BRP on dry ice by overnight carrier. Corn grain samples were stored frozen for a maximum of 161 days prior to extraction for analysis. Adequate storage stability data are available to support this study.

Residues of cyfluthrin were determined using the GC/MS-SIM method described above. Recoveries of cyfluthrin were 95-110% from control samples of grain fortified with cyfluthrin at 0.01 and 0.02 ppm. Apparent residues were <LOQ in/on all control grain samples. Adequate representative sample calculations and chromatograms were submitted. Residues of cyfluthrin were <0.01 ppm in all 6 subsamples of grain harvested 21 days following the last of four foliar applications totaling 1.0 lb ai/A (5.7x the proposed rate). As residues in grain were <0.01 ppm following foliar applications at 5.7x the proposed rate, AGF and processed commodities were not analyzed.

Conclusions:

The submitted corn grain processing study is adequate and supports the use of cyfluthrin (2 lb/gal EC) for foliar application to field corn. Residues in corn AGF and processed commodities resulting from the proposed use are unlikely to exceed the current 0.01 ppm tolerance for cyfluthrin residues in/on corn grain.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

This matter is being addressed in HED memo of 08/15/02, Y. Donovan, D262353.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

Rotational crop data supporting planting as soon as practical were reviewed by EFED in 1989/1990 based on correspondence provided by RD. although there were questions about storage stability of residues in wheat forage, the registrant provided information on stored potato and soybean leaves to resolve the issue. In a letter from George LaRocca (RD) to Mobay chemical Corporation dated 5/9/90, the labeling bearing the proposed rotational crop statement (i.e., planting as soon as practical) was accepted. HED notes that this statement is consistent with other pyrethroids, which show very little uptake of the parent compounds into rotational crops.

AGENCY MEMORANDA CITED

CB Nos.: 5039, 5040, 5041, 5242, and 5243
 DP Barcode: None
 Subject: PP's# 9F3731/9H5574: Baythroid® (Cyfluthrin) in/on Various Raw and Processed Agricultural Commodities. Evaluation of Analytical Methodology and of Residue Data.
 From: H. Fonouni
 To: G. LaRocca
 Dated: 11/17/89
 MRID(s): 41001600, 41001622, 41062000, and 41062001

CBTS Nos.: 11785, 11786, and 11787
 DP Barcodes: D190671, D190677, and D190675
 Subject: 3F4204/3H5670. Cyfluthrin in/on sugarcane. Evaluation of Residue Data and Analytical Methodology.
 From: J. Morales
 To: G. LaRocca
 Dated: 5/5/94
 MRID(s): 42710400, 42710401, 42710402, and 42710403

CBTS Nos.: 13093 and 13094
 DP Barcodes: D198397 and D198399
 Subject: PP's# 3F4309/3H5686: EPA Reg No. 3125-351. Cyfluthrin in/on Alfalfa, Sunflowers, Sweet Corn and Soybeans. Evaluation of Analytical Methods and of Residue Data.
 From: J. Garbus
 To: G. LaRocca/L. Arlington
 Dated: 5/25/95
 MRID(s): 42864601 through 42864605

CBTS Nos.: 16240
 DP Barcode: D219550
 Subject: PP's# 3F4309/3H5686: EPA Reg No. 3125-351. Cyfluthrin in/on Alfalfa, Sunflowers, Sweet Corn and Soybeans. Amendments Proposing Revised Sections B and F to Resolve Deficiencies Noted in CBTS's 5/25/95 Review of Analytical Methods and of Residue Data.
 From: J. Garbus
 To: G. LaRocca/L. Arlington
 Dated: 10/10/95
 MRID(s): None

CBTS No.: 16531
DP Barcode: D221081
Subject: PP's# 3F4309/3H5686: EPA Reg No. 3125-351. Cyfluthrin in/on Alfalfa,
Sunflowers, and Sweet Corn. Revised Section F in Response to CATS Memo of
10/10/95
From: J. Garbus
To: G. LaRocca/L. Arlington
Dated: 1/23/96
MRID(s): None



13544

050863

Chemical: Cyano(4-fluoro-3-phenoxyphenyl)methyl 3

PC Code: 128831

HED File Code 11000 Chemistry Reviews

Memo Date: ~~02/15/0087~~

File ID: DPD250002

Accession Number: 412-03-0016

08/15/08

HED Records Reference Center
09/30/2002